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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,053	02/10/2004	John J.L. Simard	MANNK.022C1	3659

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/777,053	Applicant(s) SIMARD ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 10/292,413, which claims the benefit of the filing date of provisional application 60/336,968.

New claims 26-31 have been added.

Claims 1-31 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment filed October 3, 2005, only the following outstanding ground of rejection is maintained.

The following represent new grounds of rejection that are made in response to Applicant's amendment filed October 3, 2005.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

In an effort to differentiate the claimed invention from the prior art, claim 1 as been amended to recite "an expression vector"... "that does not encode a whole tumor associated antigen." Newly added claim 28 recites the same limitation. Applicant asserts that support for this amendment to the claims can be found in paragraph [0011] of the specification. The paragraph recites "[o]ne embodiment of the invention relates to an isolated nucleic acid containing a reading frame with a first sequence encoding one or more segments of SSX-2, wherein the whole antigen is not encoded, wherein each segment contains an epitope cluster." The paragraph is completely silent regard tumor associated antigens that are not SSX-2. accordingly, said paragraph does not provide support for an amendment broadly reciting that the entire reading frame of the expression vector does not encode a whole tumor associated antigen. The

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specification provides only that the reading frame does not contain the entire SSX-2 antigen. There is no support for the broad exclusion of any other "whole tumor associated antigen." Accordingly, the recitation constitutes new matter and must be removed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 28 are ambiguous and unclear in the recitation of a "reading frame that does not encode a whole tumor associated antigen." Does the recitation refer to an entire polypeptide molecule comprising multiple antigenic sites or to individual antigens within a polypeptide molecule? The term is not adequately defined in the specification and the art presents differing opinions as to which scenario is properly descriptive of an "antigen." Clarification is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al (Nature Genetics [1994] 7(4):502-508; U on form PTO-892 of record) as evidenced by Ayyoub et al (J. Immunol. [2002] 168(4):1717-1722; U1 on form PTO-892, newly cited).

The claim is drawn to an isolated nucleic acid molecule encoding a fragment of tumor-associated antigen SSX-2 and a liberation sequence. A "liberation sequence" is defined by the instant specification at paragraph [0070] as being larger sequence that provides a context allowing the housekeeping epitope to be liberated by immunoproteasomal processing. The claim does not put any limitation regarding the size of the fragment, the composition of the fragment (i.e., whether it is a housekeeping epitope, immuno epitope or not an epitope at all) or the location/relationship of the "liberation sequence" relative to the fragment.

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Clark teaches an isolated nucleic acid that encodes the tumor-associated antigen SSX-2 (see entire document, Figure 4b in particular). While Clark is silent regarding the presence of "liberation sequences" in the sequence of the encoded protein, silence about a particular property does not necessarily constitute its absence. The SSX-2 protein comprises fragments that are inherently recognized by cytotoxic T cells, as evidenced by Ayyoub (Abstract in particular). In order to be recognized by CTL, the fragments of SSX-2 must be liberatable from the protein by an immunoproteasome in order to be presented in the context of MHC class I. therefore, SSX-2 inherently comprises a liberation sequence that allows the fragment to be presented to CTL.

The prior art teaching anticipates the claimed invention.

### *Conclusion*

4. No claim is allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.   
Patent Examiner  
January 4, 2006



DAVID SAUNDERS  
PRIMARY EXAMINER

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